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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,722	02/05/2002	Victor C. W. Tsang	6395-62261	2650

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/25/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,722

Applicant(s)

TSANG ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. The preliminary amendment filed on 2/5/02 (paper # 2) is entered. Claims 8-20 are canceled. Claims 2-7 have been amended. New claims 21-25 have been added. Claims 1-7 and 21-25 are pending in the application.

Priority

2. This application 10/072722 is a division of 09/454,753, now U.S. Patent 6379906 is acknowledged. However, applicant is advised to update the status of the priority document.

Information Disclosure Statement

3. Information Disclosure Statement filed on 2/5/02 (Paper # 3) is acknowledged and a signed copy is attached to this Office action.

Claim Rejections - 35 USC 112, Second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 5 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 are unclear whether or not the mixture of two or more peptides indicates that each peptide in the mixture has a molecular weight of e.g. 33kD or 38 kD or the mixture as a whole has the molecular weight of 33kD or 38 kD

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Claim 23 is vague in reciting, "peptide comprises a label". Does applicant intend to mean the claim to recite peptide is labeled?

Objection

6. Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In claim 25, applicant is claiming a kit comprising the composition of claim 1. However, there is no difference between claim 1 and claim 25, as both claims comprise an isolated, adult T.solium excretory/secretory polypeptide. Therefore, applicant is advised to amend the claim to recite the other components of the kit.

Claim Rejections - 35 USC 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1-7 and 21-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Wilkins et al 1997 (Annual Meeting of the American Society of Tropical Medicine and Hygiene, Lake Buena Vista, FL (USA) 7-11 December 1997).

Claims are drawn to a composition comprising an isolated, adult *T.solium* excretory secretory polypeptide, mixture of polypeptides having an approximate molecular weight 33kD (32.7), 38kD (37.8) and 42 kD (42.1), said polypeptide is immobilized on a solid phase, said peptide is labeled. Examiner viewing claim 25 is the same as claim 1.

Wilkins et al 1997 disclose an isolated adult *T.solium* excretory /secretory polypeptide from culturing adult worms in serum free medium. Excretory and secretory antigens have approximate molecular weight 33kD (32.7 kD), 38kD (37.8 kD) and 42 kD (42.1 kD) were collected from culture media from day 3 through day 12. This media comprises two to three excretory and secretory antigens from adult *T.solium* and thus read on claims 2-7. Further the prior art discloses that these antigens were identified by an immunoblot assay and thus read on claims 21-24 because in an immunoblot, antigens are immobilized nitrocellulose membranes, which reads on solid particle. Labeling peptide in an immunoblot assay is well known in the art (see abstract). The prior art anticipated the claimed invention.

9. Claims 1 and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by McManus Donald 1995 (Papua New Guinea Medical Journal, Vol.38, No.4, 287-294). Claims are drawn to a composition comprising an isolated, adult *T.solium* excretory secretory polypeptide, said polypeptide is immobilized on a solid phase, said peptide is labeled. Examiner viewing claim 25 is the same as claim 1.

McManus Donald, 1995, discloses excretory or secretory molecules in serum or CSF. Further the prior art discloses that these antigens were identified by an ELISA assay and thus

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read on claims 21-24 because in an ELISA assay antigen binds to the solid surface i.e., ELISA plate. Labeling peptide in an immuno assay is well known in the art (see abstract). The prior art anticipated the claimed invention.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1-7 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko and Ng 1998(Journal of Helminthology 72, 147-154).

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Claims are drawn to a composition and a kit comprising an isolated, adult *T.solium* excretory secretory polypeptide, mixture of polypeptides having an approximate molecular weight 33kD (32.7), 38kD (37.8) and 42 kD (42.1), said polypeptide is immobilized on a solid phase, said peptide is labeled. Examiner viewing claim 25 is the same as claim 1.

Ko and Ng teach a method for evaluation of excretory and secretory products of bladder worm *Taenia solium* by enzyme linked immunotransfer blotting (EITB). Analysis of ES products is determined by SDS-PAGE (page 148 under materials and methods: SDS-PAGE and EITB). The SDS-PAGE profile of the ES products showed the presence of at least 19 polypeptides. Three of the bands with molecular weight 19, 54 and 62 kD are heavily stained and the last one being the most prominent. These antigens are used for identifying the *T.solium* (see page 149, 2nd and third paragraph and figure 1 and 3). Thus the prior art teaches use of one to three peptides of larval excretory and secretory antigens as diagnostic antigens for detecting *T.solium*. However, the prior art does not teach adult *T.solium* excretory and secretory polypeptides and a kit comprising the same.

Ko and Ng suggest that excretory and secretory products of many helminthes are well known to contain highly specific antigens, which can be used for serodiagnostic (page 147, second paragraph) purposes. Therefore, It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use mixture of excretory and secretory antigens as taught by Ko and Ng with a reasonable expectation of success because the use of mixture of excretory and secretory polypeptides (one to three) and methodologies for detecting *T.solium* are taught by this prior art. An artisan of ordinary skills would have been motivated to use adult *Taenia* excretory and secretory antigens instead of larval antigens as used in the prior art because adult antigens are known in the art (see for example Varma et al in IDS under other publication # 9) for detecting taeniasis in humans as well as to identify carriers of taeniasis.

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Status of Claims

13. No claims are allowed.

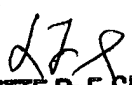
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235

Padma Baskar Ph.D.

3/19/03


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